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# Pesticide Fact Sheet Number 172: Phenmedipham

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**15. Supplementary Notes**

**16. Abstract (Limit: 200 words)**

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

**17. Document Analysis a. Descriptors**
Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

**b. Identifiers/Open-Ended Terms**

**c. COSATI Field/Group**

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EPA

# Pesticide Fact Sheet

Name of Chemical: Phenmedipham
Reason for Issuance: Registration Standard
Date Issued: March 30, 1987
Fact Sheet Number: 172

## 1. Description of Chemical

The following chemical is covered by this Registration Standard:

| | |
|---|---|
| Common name: | Phenmedipham |
| Chemical name: | 3-methoxycarbonylaminophenyl -3-methylcarbanilate |
| CAS Number: | 13684-63-4 |
| OPP (Shaughnessy) Number: | 098701 |
| Empirical Formula: | $C_{16}H_{16}N_2O_4$ |
| Trade Names: | Betanal®, GBP-1-127050®, Kemipham®, Morton EP-452®, Phenmediphame®, Schering 4072®, Schering 4075®, Schering 38584®, SN 38584®, Spinaid®. |
| Chemical Family: | Carbanilate |
| Pesticide Type: | Herbicide |
| Year of Initial Registration: | 1970 |
| Registrants of Technical Products: | Schering AG, Nor-AM Chemical Co. |

## 2. Use Patterns And Formulations

| | |
|---|---|
| Application Sites: | Terrestrial food uses (sugar beets, table beets, spinach & spinach seed). |
| Methods of Application: | Applied postemergence to foliage of weeds and crops. Primarily applied as broadcast or banded spray by ground or aerial equipment. |
| Application Rates: | Table beets, spinach: 0.5 to 1 lb, sugar beets: 0.17 to 0.61 lb (lb ai/Acre). |
| Types of Formulations: | Emulsifiable concentrate [EC] (8.0% and 15.9% a.i.) |
| Usual Carrier: | Water |

3. Science Findings

Phenmedipham did not induce neoplastic effects in chronic toxicity studies of rats. Except for weight changes in a 3 generation rat study, this chemical does not induce reproductive effects in rats. This pesticide has shown low acute oral and dermal toxicity in test animals. It is low in avian toxicity and moderately toxic to fish and aquatic invertebrates.

It does not cause the destruction of habitat of animals or non-target organisms.

Although the present data base for phenmedipham does not indicate major toxicological concerns, there are still toxicology data gaps: acute inhalation toxicity, primary eye irritation, primary dermal irritation, dermal sensitization, subchronic dermal toxicity (21-day), oncogenicity in two species, teratology in two species, mutagenicity and general metabolism have not been characterized for phenmedipham.

In addition, the environmental fate, metabolism in food crops, metabolism in ruminants and poultry for this compound have not been characterized.

Chemical Characteristics:

Phenmedipham is an odorless white to slightly colored powder at room temperature. Its melting point is 140-144° C, and its molecular weight is 300.3. Its water solubility is 3.1 mg/liter in pH 4 water at 25°C.

Toxicological Characteristics:

Acute Oral: Toxicity Category IV - > 8,000 mg/kg (male & female rats)
Acute Dermal: Toxicity Category III - > 4,000 mg/kg (male & female rats)

Chronic Toxicity:

A rat chronic feeding study with phenmedipham showed a No-Observable-Effect-Level (NOEL) for oncogenicity greater than 500 ppm (25 mg/kg), highest dose tested (HDT). Although an increase in neoplastic findings was not observed in this study up to and including a dosage level of 500 ppm (HDT), the oncogenic potential of phenmedipham cannot be ascertained in the absence of a maximum tolerated dose. Therefore, this study does not fulfill the data requirement for oncogenicity (rat). Oncogenicity studies in two species are required. The body weight gain changes noted in the high dose females during the second year are minimal evidence of systemic toxicity (less than 10% decrease). Therefore, the NOEL for systemic effects is 100 ppm with a lowest observed effect level (LOEL) for systemic effects at 500 ppm (HDT).

In a dog chronic feeding study, phenmedipham showed a NOEL of 1000 ppm (25 mg/kg, HDT). Neoplastic findings were not observed in this study up to and including a dosage level of 1,000 ppm (HDT).

Major routes of exposure: Applicators (mixer/loader) handling this pesticide.

Physiological & Biochemical Chracteristics:

Translocation: Phenmedipham is absorbed by the plant leaves and translocated to other portions of the plant.

Mechanism of pesticidal action: It is a strong inhibitor of the Hill reaction in photosynthesis.

Metabolism & Persistence in Plants & Animals: The available data are inadequate to evaluate the persistence of phenmedipham in plants and animals.

Environmental Chracteristics:

Available data are insufficient to fully assess the environmental fate and potential exposure of humans and non-target organisms to phenmedipham. Additional data are required to characterize the potential for phenmedipham to reach ground water supplies.

Ecological Characteristics:

There is sufficient information to characterize phenmedipham as having very low toxicity on an avian dietary basis for Bobwhite quail and Mallard duck. However, an avian single-dose oral toxicity study is required. There is sufficient acute toxicity information to characterize technical phenmedipham as moderately toxic to freshwater invertebrates and to both warm and cold water fish. In an acute contact study, phenmedipham was shown to be very low in toxicity to honey bees.

| | |
|---|---|
| Avian dietary toxicity:<br>(8 day diet) | (Low toxicity)<br>Bobwhite quail - > 10,000 ppm<br>Mallard duck - > 10,000 ppm |
| Freshwater fish toxicity:<br>(96-hour exposure in water) | (Moderate toxicity)<br>Bluegill - 3.98 ppm<br>Rainbow trout - 1.41 ppm |
| Aquatic invertebrate toxicity:<br>(48-hour exposure in water) | (Moderate toxicity)<br>Daphnia magna - 3.2 ppm. |

Endangered species:

No endangered species labeling is required because of the low to moderate toxicity of phenmedipham products to avian and aquatic species, and the fact that this pesticide will not readily drift from the application sites to endangered plants. In addition, treated crops are not planted in the habitat of these plants.

Tolerance Assessment

Sufficient data are available to ascertain the adequacy of the established tolerances for residues of phenmedipham in or on table beet roots and tops, sugar beet roots and tops, and spinach (40 CFR 180.278).

Tolerances for Phenmedipham have been approved for the raw agricultural commodities (RAC's) listed below.

| Crop | Tolerance(ppm) | Food Factor | mg/day(1.5kg) |
|---|---|---|---|
| Beets | 0.20 | 0.17 | 0.00052 |
| Sugar, beet roots | 0.10 | 3.64 | 0.00546 |
| Sugar, beet tops | 0.10 | 3.64 | 0.00546 |
| Spinach | 0.50 | 0.05 | 0.00038 |

The provisional acceptable daily intake (PADI) for phenmedipham is based on a 104 week rat feeding study. The systemic NOEL for for this study is 100 ppm (5 mg/kg). The systemic lowest observed effect level (LOEL) is 500 ppm (25 mg/kg/day, HDT). There is also a 104 week dog feeding study with a NOEL of greater than 1000 ppm (25 mg/kg, HDT). Utilizing a safety factor of 100, the PADI was set at 0.050 mg/kg/day. This is equivilant to a maximum permitted intake (MPI) of 3.00 mg/day for a 60 kg individual. The theoretical maximum residue contribution (TMRC) for phenmedipham in the daily diet based on the total tolerances above and a daily food intake of 1.5 kg is 0.0064 mg/day. Under these conditions, 0.21% of the PADI has been utilized.

However, data gaps exist for plant and animal metabolism, analytical methods, and storage stability. Processing studies are required for sugar beets. Since the data required for individual commodities are dependent on metabolism data, the Agency recommends that metabolism data be obtained and submitted prior to any required residue data.

There are Canadian tolerances of 0.10 ppm for phenmedipham residues in or on sugar beets and tops but no tolerances on spinach and table beets. There are no Mexican tolerances, Codex Maximum Residue Levels, or exemptions for phenmedipham on sugar beets, spinach and table beets.

Reported Pesticide Incidences

The Pesticide Incident Monitoring System (PIMS) does not have any incident involving phenmedipham at this time.

4. Summary of Regulatory Positions & Rationale:

-- The Agency has determined that phenmedipham does not exceed any of the risk criteria for adverse effects in 40 CFR, Section 154.7 at the present time. Available data indicate that phenmedipham does not promote neoplastic findings in chronic toxicity studies of rats. Except for weight changes in a 3-generation rat study, this compound does not induce reproductive effects in rats. It does not pose a risk of serious acute injury to humans, domestic animals or non-target organisms and, it does not cause the destruction of habitat of non-target organisms.

-- The Agency has determined that certain toxicological studies are required to support the reregistration of phenmedipham products: acute inhalation, primary eye irritation, primary dermal irritation, dermal sensitization, subchronic dermal toxicity (21-day), oncogenicity in two species, teratology in two species, mutagenicity and metabolism studies.

-- The Agency has determined that present precautionary statements for persons handling or applying phenmedipham products are sufficient for the labels of manufacturing-use and end-use products. Available data indicate that phenmedipham causes low oral (Category IV) and dermal (Category III) toxicities in test animals. Therefore, the labeling of these products contain statements that caution persons applying or handling this compound, give first aid instructions, and require the use of precautionary measures to ensure safe handling of the pesticide products.

-- The Agency has determined that reentry intervals for workers are not required for phenmedipham products. The low acute toxicity of this chemical does not warrant significant concern about exposure of workers reentering treated areas, according to the criteria in 40 CFR Part 158.140.

-- At this time, the Agency will defer action on ground water issues until receipt and evaluation of environmental fate data.

-- The Agency is requiring labeling which warns of potential hazards to aquatic organisms. Available acute toxicity data indicate that phenmedipham is moderately toxic to fish and aquatic invertebrates.

--The available data indicate that this pesticide, when applied at recommended rates, does not present unreasonable hazards to birds. Existing studies on this compound indicate that its dietary toxicity to birds is very low.

-- The Agency has determined that specific labeling to mitigate potential hazards to endangered species are not required. Available data indicate that phenmedipham exhibits low toxicity to avian species, and moderate toxicity to fish and aquatic invertebrates. Crops treated with this pesticide are not planted in the habitat of endangered plants. Also, this chemical will not readily drift from its application sites to the endangered plants.

-- The Agency will not require phytotoxicity data. Phenmedipham has low volatility and will not readily drift from its application sites to non-target plants and it has limited terrestrial use on minor crops.

5. Precautionary Statements

a. Manufacturing-Use Product Statements

All phenmedipham products intended for formulation into end-use products must bear the following statements:

"This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. End-Use Product Statements

The following precautionary statements must appear on all EP labels:

"This pesticide is toxic to fish and aquatic organisms. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff from treated areas may be hazardous to fish and aquatic organisms in adjacent aquatic sites. Do not contaminate water by cleaning of equipment or disposal of wastes."

6. Summary of Major Data Gaps

158.120 Product Chemistry data are required during 1987.

| | | |
|---|---|---|
| 158.125 | Residue Chemistry: | |
| 171-4 | Nature of Residue (Plant & Animal Metabolism) | October 30, 1988 |
| 171-4 | Residue Analytical Methods | July 30, 1988 |
| 171-4 | Storage Stability | July 30, 1988 |
| 171-4 | Residue Studies on Crops, Processed Food/Feed Commodities | April 30, 1989 |
| 158.135 | Toxicology: | |
| 81-3 | Acute Inhalation Toxicity (Rat) | January 30, 1988 |
| 81-4 | Primary Eye Irritation Toxicity (Rabbit) | January 30, 1988 |
| 81-5 | Primary Dermal Irritation (Rabbit) | January 30, 1988 |
| 81-6 | Dermal Sensitization (Guinea pig) | January 30, 1988 |
| 82-2 | Subchronic Dermal (21-day) | April 30, 1988 |
| 83-2 | Oncogencity (Two species) | |
| | (Mouse) | May 30, 1988 |
| | (Rat) | June 30, 1991 |
| 83-3 | Teratogenicity (Two species) | July 30, 1988 |
| 84-2 | Mutagenicity | April 30, 1988 |
| 85-1 | Metabolism | April 30, 1989 |
| 158.130 | Environmental Fate | |
| 161-1 | Hydrolysis | January 30, 1988 |
| 161-2 | Photodegradation in Water | January 30, 1988 |
| 162-2 | Anaerobic Soil Metabolism | July 30, 1989 |
| 163-1 | Mobility Studies (Leaching & Adsorption/Desorption) | April 30, 1988 |
| 164-1 | Soil Dissipation | July 30, 1989 |
| 165-1 | Rotational Crops (Confined) | July 30, 1990 |
| 165-4 | Accumulation in Fish | April 30, 1988 |
| 158.145 | Wildlife and Aquatic Organisms | |
| 71-1 | Avian Oral Toxicity | January 30, 1988 |

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